JUN 16 2003

HemoSplit Catheter
510(k) Summary of Safety and Effectiveness
21 CFR 807.92(a).

General Information:

Submitter Name:	Bard Access Systems, Inc. [Wholly owned Subsidiary of C. R. Bard, Inc.]
Address:	5425 W. Amelia Earhart Drive Salt Lake City, UT 84116
Telephone Number:	(801) 595-0700 ext. 5525
Fax Number:	(801) 595-5425
Contact Person:	Glenn Norton
Date of Preparation:	April 14, 2003

Device Information:

Device Names:	HemoSplit™ Dual Lumen Catheter
Trade Names:	HemoSplit™
Common/Usual Name:	Long-Term Hemodialysis Catheter
Classification Name:	78MSD Catheter, Hemodialysis, Implanted 21 CFR 876.5540 (b)(1) - Class III Implanted Blood Access Device
Classification Panel:	Gastroenterology and Renal

Class III – No effective date has been established for the requirement for premarket approval for the device described in paragraph (b)(1).

Predicate Devices:

- Opti-Flow (renamed HemoGlide) Long-Term Hemodialysis Catheter, K010567, clearance date 3/28/2001
- Medcomp Ash Split-Cath II Hemodialysis Catheter, K020465, clearance date 05/22/2002

Summary of Change:

The modification to the HemoGlide Long-Term Dialysis Catheter, called HemoSplit, is a redesign of the distal tip configuration in which the lumens are bifurcated at a fixed point of separation, allowing independent movement of the lumens beyond the fixed point. The body of the HemoSplit catheter has the same basic design as HemoGlide with respect to the catheter shaft, bifurcation, and extension legs. However, the catheter shaft material is changed, as arethe new material/design for the luer connector.

Device Description:

HemoSplit Long-Term Dialysis Catheters are dual lumen catheters available in straight and precurved configurations with multiple insertion lengths. HemoSplit catheter bodies are made from a polyurethane material that is radiopaque. The dual lumen shaft has a double-D cross-sectional design with a venous lumen tip opening molded to facilitate over-the-guide wire placement. The arterial and venous lumens are separated a maximum of 8cm proximal to the distal tip of the venous lumen, and are able to float freely in the blood stream. The molded bifurcation has an integral suture wing that is

suitable for use with StatLock® securement devices. Each extension leg coming out of the bifurcation has an atraumatic acetal occlusion clamp, which closes the access to the lumen. The clamps have integral tags with the priming volumes of the individual lumen printed on them. Red and blue color-coded luer connectors identify the arterial and venous lumens, respectively.

Intended Use of Devices:

The **HemoSplit™** long-term hemodialysis catheter is indicated for use in attaining short-term or long-term vascular access for hemodialysis, hemoperfusion or apheresis therapy. Access is attained via the internal jugular vein, external jugular vein, subclavian vein, or femoral vein.

Catheters greater than 40 cm are intended for femoral vein insertion.

Technological Comparison to Predicate Devices:

The technological characteristics of the HemoSplit Dual Lumen Catheter are substantially equivalent to those of the predicate HemoGlide and Ash Split-Cath II catheters in terms of intended use, application, user population, basic design, performance, labeling, packaging, and sterilization method.

510(k) Substantial Equivalence Decision Tree:

New device is compared to Marketed Device?

Yes.

Does the new device have the same indication statement as the predicates?

Yes, with minor modifications.

Does the new device have the same technological characteristics, eg. design, material, etc.?

Yes. The principles of operation and basic design are a combination of the two predicate devices. The labeling of the Split-Cath II indicates that it is made of Carbothane. The split-tip configuration is fundamentally the same as the Split-Cath II. The dual lumen bifurcated catheter body and extension legs are the same as the HemoGlide. However, the HemoGlide's acetal luer connectors have been replaced with polycarbonate (PC) luer connectors.

Could the new characteristics affect safety or effectiveness?

Yes. The split-tip configuration, the catheter body material change, and material/design change of the connector/bond could affect the safety or effectiveness of the device.

Do the new characteristics raise new types of safety and effectiveness questions?

No. Safety and effectiveness questions are the same for all long-term dialysis catheters.

Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes. Reliance was placed on recognized standards to evaluate the device's performance. (See Non-Clinical Performance Data below.)

Are performance data available to assess effects of new characteristics?

Yes. Bench testing was performed according to the referenced standards. The test results met the requirements and were compared to the predicate devices.

Do performance data demonstrate equivalence?

Yes. Performance data demonstrate that the HemoSplit Long-Term Hemodialysis Catheters are substantially equivalent to the predicate HemoGlide Long-Term Hemodialysis Catheters and Ash Split-Cath II Hemodialysis Catheters.

Non-Clinical Performance Data

As this change is being submitted via Abbreviated 510(k), the modification of the HemoGlide catheter was done with conformance to recognized standards:

ISO 594-1:1986, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General Requirements

ISO 594-2:1986, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock Fittings.

In addition, design verification testing was conducted in conformance of FDA's *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, dated 3/16/95*, to in-house protocols, and performed or evaluated based on the following FDA Guidance's and recognized standards:

- *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, dated 3/16/95*
- *ISO 10555-1:1997, Sterile, single-use intravascular catheters, Part 1. General requirements*
- *ISO 10555-3:1997, Sterile, single-use intravascular catheters, Part 3. Central venous catheters*
- *AAMI/ANSI/ISO-10993-1: 1997, Biological evaluation of medical devices – Part 1: Evaluation and testing, and the FDA Modified ISO 10993 Test Profile*
- *AAMI/ANSI/ISO 11135*:1994, *Medical devices – Validation and routine control of ethylene oxide sterilization*

Results from biocompatibility testing met the requirements of ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing" and the FDA Modified ISO 10993 Test Profile for externally communicating blood contacting long term devices.

All test results confirm the modified device to be substantially equivalent to the predicate devices.

Conclusions:

The HemoSplit Long-Term Dialysis Catheter met all the performance criteria of the tests performed and, based on FDA's decision tree, is substantially equivalent to the predicate Opti-Flow Long-Term Dialysis Catheter, K010567, concurrence date March 28, 2001, and the Medcomp Ash Split-Cath II Hemodialysis Catheter, K020465, clearance date 05/22/2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 2003

Mr. Glenn Norton
Senior Regulatory Affairs Specialist
Bard Access Systems, Inc.
5425 W. Amelia Earhart Drive
SALT LAKE CITY UT 84116

Re: K030020
Trade/Device Name: HemoSplit Long-Term Hemodialysis Catheter
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: 78 MSD
Dated: April 14, 2003
Received: April 15, 2003

Dear Mr. Norton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note*: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

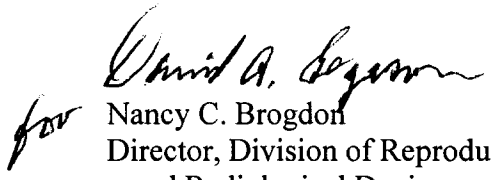
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation, please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/dsma/dsmamain.html

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

HemoSplit™ Long-Term Catheter

INDICATION(S) FOR USE STATEMENT*

I state in my capacity as Senior Regulatory Affairs Specialist of Bard Access Systems, that this notification [510(k)] for the HemoSplit™ Long-Term Hemodialysis Catheter is indicated for the following:

*"The **HemoSplit™** long-term hemodialysis catheter is indicated for use in attaining short-term or long-term vascular access for hemodialysis, hemoperfusion or apheresis therapy. Access is attained via the internal jugular vein, external jugular vein, subclavian vein, or femoral vein.*

Catheters greater than 40 cm are intended for femoral vein insertion."

Signature of 510(k) Submitter: _____

Printed Name of Submitter: Glenn Norton

Date: 4-14-03

*Suggested language and format to meet the requirements of sections 513(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and sections 807.92(a)(5) and 801.4 of the Code of Federal Regulations, Title 21.

Concurrence of Office of Device Evaluation

510(k) Number K030020

Division Sign-Off
Office of Device Evaluation _____

Prescription Use ✓